

Implementation of EU legislation on counterfeit/falsified medicines: aspects of the pharmaceutical industry

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Introduction

In the last decade, dealing with counterfeit/falsified medicines has been a major challenge for both, health regulators and the pharmaceutical industry. Information from the World Health Organization shows that in recent decades the global drug market is full of counterfeit drugs: 10% of global drugs are falsified, and in some countries, the figure reaches 30% to 60%. In developed countries with effective regulatory systems in place, the percentage of counterfeit drugs detected in the legitimate supply chain is around 1%. About 50% of the drugs purchased online from illegal websites are counterfeit. This imposes the need for a serious approach to combating the influx of counterfeit drugs by all stakeholders, governments, health regulators, the pharmaceutical industry, police, customs and the judiciary.

Counterfeit/falsified drugs pose a significant threat to public health globally, causing ill health, disability and death. On the other hand, counterfeit drugs have economic consequences for the pharmaceutical industry of innovative (branded) drugs and generic drugs (Williams and McKnight, 2014).

Materials and methods

The European Union (EU) strategy to prevent counterfeiting of medicines covers several levels:

- establishment of a regulatory framework;
- law enforcement (police, customs, judiciary);
- multisectoral training for representatives of member states;
- at the pharmaceutical level, the inspection of the production sites is increased, the quality of the drugs on the market is monitored as well as the suspicious samples

through the participation of the OMCL laboratories and the GEON network, the reports for pharmacovigilance from the users are monitored;

- public awareness campaigns are organized.

With the entry into force of EU Directive 2011/62, harmonized security and control measures have been introduced throughout Europe in order to prevent the entry of counterfeit/falsified drugs into the legal supply chain of medicinal products in the Member States of the European Union. These measures provide easier identification of counterfeit drugs and improve the verification and control of EU borders and within the EU. The Directive lays down, inter alia, the rules for the production, import, placing on the market, as well as the wholesale trade of medicines in the European Union, as well as the rules concerning the active substances.

The obligations of the pharmaceutical industry under the Directive are the renewal of production lines; redesign of the outer packaging for the application of safety features (serialization); establishing adequate quality safety features in accordance with technical specifications (GS1); verification of security features before distribution on the market with appropriate 2D scanners; establishing, managing and maintaining a database of unique identification codes as well as verification systems; upgrading the software system in order to connect to the database for the unique identifier; and information to the EMA on the safety features introduced by the pharmaceutical company (EU Directive 2011/62).

Results and discussion

Implementation of the EU Counterfeiting Directive and Regulation for falsified drugs is a major challenge (capital investment) for the pharmaceutical industry, as it has an impact on various steps in the drug production process, but is still a great benefit for pharmaceutical

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companies in the fight against counterfeiting. (EMA, 2019) The pharmaceutical industry undertakes certain activities in the prevention of counterfeiting of drugs while forming working groups / teams to fight / coordination bodies whose role is to establish a strategy and take action in the fight against counterfeiting of drugs in order to secure its product lines and reduce the impact of forgery on the company. These teams / coordination bodies are composed of experts from various fields such as: pharmacovigilance, regulation, production, quality assurance, industrial, medical and legal affairs and communication. The pharmaceutical industry strategy for preventing counterfeiting consists of the following steps:

1. Product safety and distribution chain
2. Investigations and implementation of activities
3. Advocacy, engagement and awareness raising

1. The safety of the products and the distribution chain of a pharmaceutical company is achieved by introducing specific characteristics that contain identification marks / objects and can be visible (overt) to distributors and patients and invisible (covert), which are known only to the pharmaceutical company. As well as the introduction of sophisticated technology for transparency of the distribution chain in real time (EU Regulation 2016/161).

2. In terms of strategy for investigations and activities, companies set up specially designed laboratories to combat counterfeiting. The purpose of these laboratories is to detect counterfeit drugs through an established, dedicated team of experts using advanced technologies. The specialized laboratory within the pharmaceutical company aims at examining suspicious samples including visual inspection of the packaging and instructions for use, as well as conducting chemical analysis with the most sophisticated analytical techniques for qualitative and quantitative identification.

Detection of counterfeiting in chemical laboratories is relatively simple, but much more information can be obtained from the analysis made by a pharmaceutical forensic research strategy conducted by specialized departments in the pharmaceutical industry called Pharmaceutical intelligence.

This strategy is based on the formation of a file (profile) of the drug based on available information about the drug and data from conducted analytical tests and their organization in a systematic model, database, which will allow comparison of data on suspected drugs for falsifying data from authentic drugs. At the end of the analysis, a summary report is prepared with all the data on the counterfeit product and it is sent to the coordinating body / anti-counterfeiting team, which further implements activities with regulatory bodies and government bodies (police, judiciary, customs).

3. Pharmaceutical companies undertake various activities, campaigns, brochures, advertisements, educational programs to raise public awareness about the dangers of counterfeit drugs, in constant cooperation with national institutions and organizations (customs services,

pharmaceutical manufacturers, wholesalers and consumer groups) and international organizations, (United Nations, UN, WHO, Interpol, etc.). Mutual cooperation and sharing of information enables increase of public awareness among patients, but also among all stakeholders from the phenomenon of drug counterfeiting (WHO, 2018).

Conclusion

The European Union regulatory measure against the increasing number of counterfeit/falsified medicines present in the legal supply chain within the Member States is the counterfeit/falsified medicines Directive 2011/62 / EU, according to which the manufacturers of medicines are obliged to implement safety features of medicines.

The question is "What should pharmaceutical professionals strive for and do to protect their company and patients from the effects of counterfeit drugs"?

The answer is to identify the products with the highest risk of counterfeiting and to ensure their legitimate distribution chain in the best possible way. This will certainly be made possible through combination of knowledge (information, training, instructions), design (visible and traceable), process (step by step) and system (constant correlation with stakeholders)

The key to success in the fight against counterfeiting of drugs lies in the constant cooperation at national and international level between the regulatory bodies in health, police, customs, judiciary and manufacturers, distribution system (wholesalers, retailers), health workers, and patients. which cooperation will be enabled:

1. Protection of patients' health
2. Protection of the brand of the pharmaceutical company
3. Trust in the health system

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